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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,644	12/05/2003	Shuji Jinno	13709-002003	9219
26171 7590 09/10/2007 FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER SACKEY, EBENEZER O	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 09/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/727,644		JINNO ET AL.	
	Examiner		Art Unit	
	EBENEZER SACKEY		1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 17-23 and 26-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12, 17-19, 34-48, 53, 54 and 56-68 is/are allowed.
- 6) ☒ Claim(s) 20-23, 26-33 and 49-52 is/are rejected.
- 7) ☒ Claim(s) 55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-12, 17-23 and 26-68 are pending.

This is in response to applicants' amendment filed on 05/09/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-12, 17-23 and 26-68 under 35 U.S.C. 112 second paragraph has been withdrawn.

However, new rejections under 35 U.S.C. 112 first and second paragraph follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims recite various tricyclic compounds where substituents R₂ or R₃ are defined as any one of a heterocycle, a substituted heterocycle, an aromatic ring or a substituted aromatic ring. However, the specification only teaches the use of furan,

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benzofuran, pyridine, thiophene and substituted phenyl. Therefore, the specification is not adequately enabled for the scope of heterocycle, a substituted heterocycle, an aromatic ring or a substituted aromatic ring embraced by the claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is the use of substituted tricyclic fused heterocyclic derivatives of formula (I) for the relaxation of tracheal smooth muscles. As stated, however, the activity of any and all heterocyclic and aromatic compound is intended. However, the recited claims are so generic that there is no reasonable basis for assuming that the myriad of compounds embraced herein by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same.

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The rejection is directed to the scope at all R_2 or R_3 variables which include optionally substituted derivatives of nonlimiting scope as well as those R_2 or R_3 which embrace a variety of heterocyclic and aromatic compounds directly attached to the dibenzo[b,f]oxepin ring. Note *In re Surrey*, 151 U.S.P.Q. 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure sensitive arts such as the pharmaceutical art.

2) State of the Prior art.

The compounds are substituted dibenzo[b,f,]oxapin derivatives. While such compounds are known as evident from the specification, they describe a small portion of the compounds claimed herein and thus, do not evidence the many structural permutations permitted in the instant scope for use in the prior art.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would first need to determine the type of heterocyclic or aromatic compound to employ, and then determine which of the compounds to use.

4) Level of predictability in the art.

The invention is pharmaceutical in nature as it involves the relaxation of tracheal smooth muscles. Br. J. Pharm, cited in the specification teaches compounds similar to the instantly claimed compounds, which are antagonists for contractile long muscles. Thus, there is no absolute predictability even in view of the seemingly high level of skill in the art. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved" and physiological activity is generally considered to be unpredictable. See *In re Fisher*, 166 U.S.P.Q. 18.

5) Amount of direction and guidance provided by the inventor.

The compounds made and tested are not representative of the instant scope but are closer to each other than to the remaining scope being mainly within the scope of Examples 1,3, 5, 11, 15, 57, 58, 95, 168 and 170.

6) Existence of working examples.

As discussed above, working example is found in the Examples provided above. Applicant's limited working examples do not enable one of ordinary skill in the art to employ the numerous amounts of compounds encompassed by the instant invention.

7) Breadth of claims.

The claims cover compounds easily in the millions based on the permutations pointed out.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Due to the unpredictability in the chemical art, it is noted that each embodiment of the invention is required to be individually assessed for activity to determine which compounds exhibit the desired chemical activity.

Hence, the specification fails to provide sufficient support of the broad prevention of protein Kinase related diseases claimed herein. As a result necessitating one of ordinary skill in the art to perform an exhaustive search to determine which heterocyclic compound or aromatic compound can be employed to practice the claimed invention.

Genentec Inc. V. Novo Nordisk A/S (CAFC) 42 USPQ 2D 1001, states that:

"a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test which substance(s) or agent(s) can be employed in the instant claim, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-23 and 26-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 20-23 do not further limit the scope of claim 19 since reciting intended uses in such claims is not given any patentable weight. Note *In re Tuominen*, 213 U.S.P.Q. 89 and MPEP 2111.02.
2. Claims 20-23 also recites the limitation "the tracheal smooth muscles, inhibitory effect, the anti-asthmatic respectively" in the claims. There is insufficient antecedent basis for these limitations in the claims.
2. It is not clear what the scope of R₅ to R₈ is in claim 33. The same rejection applies to claims 26-32 in the definition of X, Y, W₁, W₂, R₁ to R₄.

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Claim Objection

In claim 55, under the definition of W₉, "group" has been misspelled. Correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

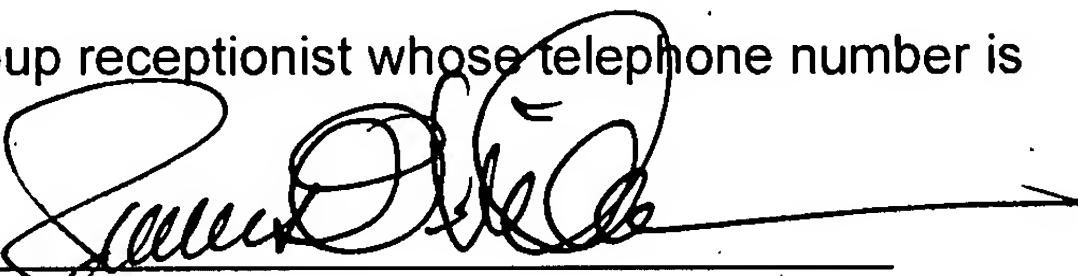
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is

(571) 272-1600.

EOS

August 24, 2007


James O. Wilson
Supervisory Patent Examiner
Art Unit 1624, Group 1600
Technology Center 1